REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 33 and 40-55 are cancelled, claim 34 is amended and claims 56-72 are added, whereby claims 27-32, 34-39 and 56-72 will be pending, with claims 27, 68 and 72 being independent claims. Claim 30 is withdrawn from consideration.

Support for the amended and new claims can be found throughout the present specification and the original claims.

Applicants emphasize that the cancellation of (non-elected) claims 40-55 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute these claims in one or more continuation and/or divisional applications.

Summary of Office Action

The restriction and election of species requirements have been made final.

Claims 28 and 36 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement.

Claims 27, 28, 31, 36 and 37 rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 0 212 681 (hereafter "EP'681").

Claims 27, 28, 31, 36 and 39 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,839,174 to Baker et al. (hereafter "BAKER").

Claim 29 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 or BAKER, each in view of Ganster et al., U.S. Patent No. 6,191,216 (hereafter "GANSTER").

Claim 32 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 or BAKER, each in view of Hobson et al., U.S. Patent No. 6,399,092 (hereafter "HOBSON").

Claims 33, 35, 38 and 39 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of U.S. Patent No. 5,866,157 to Higo et al. (hereafter "HIGO").

Claims 33, 35 and 38 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BAKER in view of HIGO.

Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 and BAKER, each in view of U.S. Patent No. 6,630,442 to Hersh (hereafter "HERSH").

Claims 33 and 35 rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 and BAKER, each in view of EP 1 059 032 (hereafter "EP'032").

Response to Office Action

Withdrawal of the rejections of record is respectfully requested in view of the foregoing amendments and the following remarks.

Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 28 and 36 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The rejection alleges that the rejected claims have introduced new matter that allegedly is not described in the specification as originally filed.

Applicants respectfully traverse this rejection. Regarding claim 28, Example 7 and the results listed in Table 2 of the present specification may, for example, be referred to. Specifically, as pointed out in Example 7, the results summarized in Table 2 show that after application of the active ingredient the bond strength (to steel) of the polyurethane matrix returned to its original level. In other words, the first side of the matrix substantially retained its original adhesive strength after application of the active ingredient, as recited in present claim 28.

Regarding the concentration range recited in claim 36, the Examiner's attention is directed to, e.g., original claim 8, wherein the concentration range of claim 36 is recited.

Applicants submit that for at least all of the foregoing reasons, the rejections of claims 28 and 36 under 35 U.S.C. § 112, first paragraph, are without merit and should be withdrawn, which action is respectfully requested.

Response to Rejection under 35 U.S.C. § 102b) over EP'681

Claims 27, 28, 31, 36 and 37 rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP'681.

Applicants respectfully traverse this rejection. Specifically, it is pointed out that independent claim 27 recites, *inter alia*, that the matrix of the patch of the present invention is self-adhesive.

EP'681 fails to disclose a self-adhesive matrix and for this reason alone, is unable to anticipate the subject matter of any of the claims submitted herewith.

That the matrix of the drug releasing member of the drug release system of EP'681 is not self-adhesive is apparent from the fact that the drug releasing member of the patch of EP'681 is used in combination with a pressure sensitive adhesive, which clearly indicates that the drug releasing member itself lacks self-adhesiveness.

For example, in the paragraph bridging columns 5 and 6 of EP'681 it is stated with reference to the drawing that "the preferred embodiment of the drug release system of the present invention is a medical patch 10 comprising successive layers of an oxygen and water vapor permeable polyurethane substrate 12, a pressure sensitive adhesive 14, and the above-described drug releasing member 16. The medical patch may optionally be provided with a second layer of adhesive 18 on the exposed side of the drug releasing member should it be desired that the system stick to the site on which it is placed." Claims 12 and 13 of EP'681 may also be referred to in this regard.

Further, in the last paragraph of column 8 and the first two paragraphs of column 9 of EP'681 the production of a corresponding patch is described and specific examples of pressure-sensitive adhesives for use in the layers 14 and 18 (polyacrylate or polyvinylethyl ether blend) are provided.

Since the drug releasing member of the device of EP'681 fails to be self-adhesive, it is self-evident that this member does not retain its original adhesive strength after application of the drug on the side that is to come into contact with the skin as recited in, e.g., present dependent claim 28.

From the comments in the last paragraph of page 14 of the present Office Action it appears that the Examiner takes the position that since present claim 27 does not recite a specific

polyurethane, its scope is broad enough to cover the use of any polyurethane and thus, also the polyurethane employed in EP'683. The Office further asserts that "EP'681 teaches the same polyurethane comprising the same ingredient as claimed by applicants, therefore, the adhesive properties are inherent to the same polyurethane."

Applicants are unable to see where EP'681 discloses " the same polyurethane comprising the same ingredient as claimed by applicants". At any rate, in view of the passages of EP'683 pointed out above it cannot reasonably be disputed that the polyurethane of EP'681 is not self-adhesive. Applicants further note that the Examiner has not provided any evidence whatsoever that each and every polyurethane is self-adhesive.

Applicants also point out that claim 27 recites, *inter alia*, that the polyurethane matrix is absorbent, that the active ingredient has been applied (in dissolved or liquid form) to the first side (intended for skin or wound contact) of the polyurethane matrix and that the first side of the polyurethane matrix remains adhesive after application of the active ingredient. None of these elements can be found in EP'681, either.

Specifically, EP'681 does not disclose the application of an active ingredient to a preformed (and absorbent) polyurethane matrix. Rather, EP'681 describes combining an active ingredient with a radiation-curable oligomer and subsequently curing the oligomer to provide a cured polyurethane matrix with the active ingredient incorporated therein. In this regard, col. 4, lines 5-28 and 46-51, col. 5, lines 15-40 and claim 6 of EP'681 may, for example, be referred to.

Of course, since the active ingredient of EP'681 is not applied to a preformed polyurethane matrix (let alone to a side thereof which is intended for skin or wound contact), it is impossible for

the polyurethane to remain adhesive after the application of the active ingredient.

Applicants submit that for at least all of the foregoing reasons, the rejection of claims 27, 28, 31, 36 and 37 under 35 U.S.C. § 102(b) over EP'681 is clearly without merit, wherefore withdrawal thereof is warranted and respectfully requested.

Response to Rejection under 35 U.S.C. § 102(b) over BAKER

Claims 27, 28, 31, 36 and 39 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by BAKER.

Applicants respectfully traverse this rejection as well. In particular, it is again pointed out that independent claim 27 recites that the polyurethane matrix of the claimed patch is self-adhesive. BAKER neither teaches nor suggests a self-adhesive polyurethane matrix and for this reason alone, is unable to anticipate the subject matter of any of the present claims.

Specifically, the controlled transdermal delivery system for nicotine disclosed by BAKER comprises an impermeable backing layer, a polyurethane matrix layer which contains nicotine and an adhesive skin-contacting member. The adhesive skin-contacting member holds the patch in contact with the skin of the wearer and may, for example, be an acrylic- or silicone-based adhesive or polyisobutylene, an amine-resistant adhesive being preferred. See, e.g., abstract, col. 2, lines 55-59, col. 3, lines 1-18, col. 4, lines 32-45, col. 6, lines 9-14 and the claims of BAKER.

Since the polyurethane matrix layer of the device of BAKER clearly is not self-adhesive, it is self-evident that this member does not retain its (lacking) original adhesive strength after application of the drug on the side that is to come into contact with the skin (as recited in present claim 28).

From the comments in the last paragraph of page 14 of the present Office Action it appears

that the Examiner takes the position that since present claim 27 does not recite a specific polyurethane its scope is broad enough to cover the use of any polyurethane and thus, also the polyurethane employed by BAKER. The Office also notes the expression "comprising" in the present claims permits the presence of skin adhesive layers.

Applicants are unable to see what the fact that the present claims do not exclude the presence of additional skin-adhesive layers has to do with the alleged anticipation of claims 27, 28, 31, 36 and 39 by BAKER. Even if such additional layers were present, the fact remains that present claim 27 recites that the polyurethane matrix is self-adhesive and that the polyurethane employed by BAKER lacks this property. Applicants also note that it cannot reasonably be asserted that each and every polyurethane is self-adhesive.

Applicants further point out that claim 27 recites, *inter alia*, that the polyurethane matrix is absorbent, that the active ingredient has been applied to the first side of the polyurethane matrix and that the first side of the polyurethane matrix remains adhesive after application of the active ingredient. None of these elements can be found in BAKER, either.

Specifically, BAKER fails to disclose the application of an active ingredient to a preformed (and absorbent) polyurethane matrix. Rather, the only active ingredient used by BAKER, i.e., nicotine, is added to a dissolved polyurethane. For example, in col. 3, lines 19-26 BAKER states (emphasis added):

> The nicotine-loaded matrix is prepared by dissolving a polyether-type polyurethane in an appropriate solvent, adding liquid nicotine and homogenizing the mixture. The matrix mixture is then cast onto the backing material by any of the techniques for polymer casting known in the art. After curing, a thin adhesive film is cast onto the matrix, or double-sided medical adhesive tape is attached.

In this regard, see also the Examples of BAKER. Of course, since the nicotine of BAKER is not applied to a preformed polyurethane matrix (let alone to a side thereof which is intended for skin or wound contact), it is impossible for the polyurethane to remain adhesive after the application of the nicotine.

Applicants respectfully submit that for at least all of the foregoing reasons, the rejection of claims 27, 28, 31, 36 and 39 U.S.C. § 102(b) over BAKER is clearly without merit and should therefore be withdrawn as well.

Response to Rejection under 35 U.S.C. § 103(a) over EP'681/BAKER in View of GANSTER

Claim 29 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 or BAKER, each in view of GANSTER. The rejection essentially asserts that GANSTER discloses a polyurethane of the type recited in present claim 29 and that it would allegedly have been obvious for one of ordinary skill in the art to replace the polyurethanes used by EP'681 and BAKER by the polyurethanes disclosed in GANSTER.

Applicants respectfully disagree with the Examiner in this regard as well. Specifically, according to EP'681 not a polyurethane, but a polyurethane-forming oligomer that can be cured, without releasing heat, by exposing it to actinic radiation must be employed (see, e.g., abstract and col. 4, lines 11-15, of EP'681). Applicants are unable to see that the polyurethane of GANSTER is an oligomer, let alone an oligomer that is curable by actinic radiation. For this reason alone, there is no apparent reason for one of ordinary skill in the art to employ the polyurethanes of GANSTER instead of the curable oligomers disclosed by EP'681.

Regarding BAKER, it is noted that this document emphasizes the presence of a skin-contacting adhesive layer (see, e.g., abstract and the claims of BAKER), wherefore there is no apparent reason for the polyurethane employed by BAKER to be adhesive and thus, there is also no need to employ the self-adhesive polyurethanes of GANSTER in the system of BAKER.

At any rate, even if one were to assume, *arguendo*, that there is a motivation for one of ordinary skill in the art to combine the teachings of EP'681 or BAKER with the teaching of GANSTER, such a combination would not result in the subject matter of dependent claim 29. Specifically, it is not seen that GANSTER cures any of the deficiencies of EP'681 and BAKER set forth above.

For example, GANSTER fails to provide any motivation whatsoever to replace the procedures for preparing an active ingredient containing polyurethane matrix described in EP'681 and BAKER (i.e., combining an actinic radiation curable oligomer with the active ingredient and then curing the oligomer or combining a polyurethane solution with the active ingredient and thereafter allowing the solvent to evaporate, respectively) by the procedure recited in present independent claim 27, e.g., applying the active ingredient in liquid or dissolved form to a side of an already preformed polyurethane matrix. In fact, GANSTER does not appear to teach or suggest the incorporation of an active ingredient in the polyurethanes disclosed therein at all.

In view of the forgoing, it is submitted that the rejection of claim 29 under 35 U.S.C. § 103(a) over EP'681/BAKER in view of GANSTER is unwarranted as well, wherefore withdrawal thereof is respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a) over EP'681/BAKER in View of HOBSON

Claim 32 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 or BAKER, each in view of HOBSON. The rejection alleges that HOBSON teaches a wound dressing superabsorbent polymer and active ingredient that when applied to the skin absorbs fluid and slowly releases the active agent into the skin, wherefore it would allegedly have been obvious to one of ordinary skill in the art to provide a drug releasing system as disclosed in EP'681 or BAKER and to further add superabsorbent to the drug containing matrix.

Applicants respectfully traverse this rejection as well. In particular, Applicants are unable to see which useful purpose a superabsorbent would serve in the transdermal delivery system for nicotine administration disclosed by BAKER. Such a transdermal delivery system clearly is not intended to be placed on a wound or any other part of the skin where the absorption of liquids is desirable. Accordingly, there is no apparent reason for one of ordinary skill in the art to incorporate an absorbent, let alone a superabsorbent, into the transdermal delivery system of BAKER.

Regarding EP'681, the Examiner's attention is directed to, e.g. col. 5, lines 28-53 thereof where it is stated (emphases added):

> ... Stated another way, any drug that functions in its intended manner after exposure to actinic radiation is operable in the present drug release system. For reasons which follow, the drug also must be water soluble.
>
> The cured polyurethane product or drug releasing member is crystal clear, biocompatible, soft and elastomeric and serves to release the incorporated drug in a controlled, sustained manner while protecting the portion of the incorporated drug yet to be released. The cured polyurethane is a solid and contains the selected drug dispersed throughout the polyurethane. Since the polyurethane of the drug releasing member is somewhat hydrophilic, it absorbs water vapor evaporating from the skin of the wearer. As the water vapor permeates through the polyurethane, it condenses to water and dissolves the drug. The flow of the drug to the wearer of the medical patch proceeds in a controlled sustained manner because of the concentration differential. That is, the drug will flow out of the polyurethane where there is a high

> concentration of the drug and into the skin where there is a low concentration of the drug. In addition, the release is controlled by the size of the molecular pores which are formed in the polyurethane.

In other words, the above passage of EP'681 makes it clear that the presence of water is essential for the functioning of the delivery system disclosed therein. Accordingly, the presence of a superabsorbent in this system would not only be superfluous but harmful in that the superabsorbent can be expected to absorb the water that is needed for dissolving the drug inside the matrix and for transporting it from inside the matrix to the skin. Accordingly, there is no apparent reason but rather a disincentive for one of ordinary skill in the art to incorporate a superabsorbent into the drug delivery system according to EP'681.

Applicants further note that even if one were to assume, *arguendo*, that there is a motivation for one of ordinary skill in the art to combine the teachings of EP'681 or BAKER with the teaching of HOBSON, such a combination would not result in the subject matter of dependent claim 32. Specifically, it is not seen that HOBSON cures any of the deficiencies of EP'681 and BAKER set forth above.

For example, HOBSON fails to provide any motivation whatsoever to replace the procedures for preparing an active ingredient containing polyurethane matrix described in EP'681 and BAKER (i.e., combining an actinic radiation curable oligomer with the active ingredient and then curing the oligomer or combining a polyurethane solution with the active ingredient and thereafter allowing the solvent to evaporate) by the procedure recited in present independent claim 27, e.g., applying the active ingredient in liquid or dissolved form to a side of an already preformed polyurethane matrix. In fact, HOBSON is not even concerned with polyurethanes, but with superabsorbent polymers.

Applicants respectfully submit that at least for all of the foregoing reasons, the rejection of claim 32 under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681/BAKER in view of HOBSON is without merit and should be withdrawn as well.

Response to Remaining Rejections under 35 U.S.C. § 103(a)

Dependent claims 33, 35, 38 and 39 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of HIGO. Claims 33, 35 and 38 are also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BAKER in view of HIGO.

Further, dependent claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 and BAKER, each in view of HERSH, and dependent claims 33 and 35 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over any of EP'681 and BAKER, each in view of EP'032.

Applicants submit that even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to combine the teachings of EP'681 or BAKER with any of the teachings of HIGO, HERSH and EP'032, this would not result in the subject matter of any of the present claims. Specifically, HIGO, HERSH and EP'032 fail to cure the deficiencies of EP'681 or BAKER set forth above.

For example, HIGO, HERSH and EP'032 fail to provide any motivation whatsoever to replace the procedures for preparing an active ingredient containing polyurethane matrix described in EP'681 and BAKER (i.e., combining an actinic radiation curable oligomer with the active ingredient and then curing the oligomer or combining a polyurethane solution with the active ingredient and

thereafter allowing the solvent to evaporate) by the procedure recited in present independent claim 27, e.g., applying the active ingredient in liquid or dissolved form to a side of an already preformed polyurethane matrix. On the contrary, all of the numerous Examples of HIGO, i.e., the only document which is concerned with a patch at all, illustrate procedures wherein the active ingredient is incorporated in the composition for making the matrix (either by melt blending or solution blending), similar to what is disclosed by EP'681 and BAKER.

Applicants additionally submit that contrary to what is alleged in the next-to-last paragraph of page 10 and the last paragraph of page 11 of the present Office Action, one of ordinary skill in the art would not have been motivated to use lidocaine in the matrices of EP'681 and BAKER, respectively. For example, according to col. 5, lines 31/32 of EP'681, the drug used therein must be water soluble. Applicants are not aware that lidocaine is a water soluble drug, and neither has the Examiner provided any evidence in this respect.

Further, the disclosure of BAKER is limited to the transdermal delivery of nicotine and nowhere in BAKER is there any suggestion, let alone teaching, that drugs which are significantly different from nicotine both in structure and activity (like lidocaine) can be delivered by means of the same matrix as that used by BAKER for nicotine.

Applicants also disagree with the Examiner that menthol qualifies as essential oil (see, e.g., page 10, 3rd paragraph of the present Office Action). As is well known to one of ordinary skill in the art, menthol is a defined covalent organic compound which is solid at room temperature.

Applicants further note that the Examiner has not explained why one of ordinary skill in the art looking for drugs which may be incorporated into the polyurethane matrices of EP'681 and

BAKER would without hindsight consult documents which do not even disclose matrices, let alone polyurethane matrices, such as HERSH and EP'032.

Specifically, HERSH describes a composition of glutathione and selenium, as a selenoamino acid or selenium yeast extract and an epidermal growth factor in a topical carrier and a method of using the composition to reduce and repair skin damage, resulting from aesthetic (exfoliation and chemical peels) and surgical (laser and other therapies) procedures and other chemical and thermal burns to the cutaneous tissues (see abstract of HERSH).

EP'032 describes a disinfecting wet wipe for wiping various surfaces, preferably hard surfaces, which wipe comprises man-made fibers (see abstract of EP'032).

Applicants respectfully submit that for at least all of the foregoing reasons, EP'681 and BAKER in view of any of HIGO, HERSH and EP'032 also fail to render obvious the subject matter of any of the claims submitted herewith, wherefore a rejection of these claims under 35 U.S.C. § 103(a) over any combinations of these documents is unwarranted as well.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

P30868.A03

Respectfully submitted,
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